

**Trust Board Meeting in Public: Wednesday 17 January 2018**

**TB2018.15**

<b>Title</b>	<b>2016-17 Research and Development Governance and Performance Annual Report</b>
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<b>Status</b>	For information
<b>History</b>	This is an Annual Report

<b>Board Lead</b>	<b>Dr Tony Berendt, Medical Director</b>			
<b>Key purpose</b>	Strategy	<b>Assurance</b>	Policy	<b>Performance</b>

## Executive Summary

1. This paper presents the Research and Development Governance and Performance Report.
2. The Oxford BRC was one of the 20 successful BRCs throughout England awarded competitive funding for 2017 to 2022. This partnership has been awarded new funding of £113.7m over the next five years, to address major NHS and global healthcare challenges, and to take advantage of new research opportunities and technologies. This is the third round of NIHR funding that the Oxford BRC has received since its first grant in 2007 and the renewal brings with it an expansion on the Research Themes from 14 to 20, including new areas such as obesity and respiratory medicine.
3. The OUH's clinical research activity continues to increase, hosting more than 1800 clinical research studies, including more than 500 clinical trials of investigational medicinal products and over 100 clinical investigations or other studies of medical devices. These activities are supported by annual revenues of £55m. OUH maintains a consistent position as a national leader amongst the most research-active Trusts in the key NIHR performance metrics including overall patient recruitment, time to recruit the first patient and recruitment to time and target.
4. The introduction of the Health Research Authority (HRA) approvals process in April 2016 represented a significant change to research governance nationally, and has had a dramatic effect on the business of the OUH-University Joint Research Office JRO, both for the University and Trust. Initial difficulties with implementation have been allayed through good communications with representatives of HRA. Over time, it is expected the level of governance review required locally can be reduced, allowing more time to be invested in capacity and capability assessment for new projects and other initiatives designed to raise awareness of research and its benefits across the entire Trust.
5. Operationally, the Joint Research Office, comprising over 80 members of staff from both OUH and University of Oxford, supports all joint research across the partnership. The JRO held a successful away day workshop in March 2017, which also involved R&D-related staff from the other Oxford Academic Health Science Centre organisations (Oxford Brookes University and Oxford Health NHS Foundation Trust) as well as the Thames Valley & South Midlands Clinical Research Network. This helped prepare for the challenges and opportunities that will arise due to changes in the accommodation of these organisations expected during the year ahead.
6. The Studyline research project and portfolio management system, developed by the Oxford JRO, helps manage the large clinical research portfolio. Studyline supports clinical research management and oversight activities as well as providing good governance and helps ensure the Trust meets its national performance metrics set by the NIHR. Studyline is also being adopted as the Local Portfolio Management System (LPMS) across all Trusts in the Thames Valley & South Midlands CRN.
- 7. Recommendation**  
The Trust Board is asked to note this report.

## 1. NIHR Oxford Biomedical Research Centre

### 1.1 NIHR Oxford BRC Funding Award

The NIHR Oxford Biomedical Research Centre (BRC) was £113.7m in the 2016 BRC competition to carry out translational medical research from 2017 to 2022, its third round of funding since its first grant in 2007. It had previously received £57m from the National Institute for Health Research (NIHR) in 2007, and then a further £95.5m in 2012.

The award of this third funding award was a recognition of Oxford's outstanding contribution to healthcare research, and confirmed its position as one of the largest NHS/university partnerships in the UK and comparable with any academic medical centre worldwide.

The renewal of the Oxford BRC brings with it an expansion of the research conducted in Oxford with NIHR funding, with the number of Research Themes expanded from 14 to 20, including new areas such as obesity and respiratory medicine.

Two noteworthy aspects of the new BRC themes are:

- The creation of four Cross-cutting Themes (Molecular Diagnostics; Clinical Informatics & Big Data; Imaging; Partnerships for Health, Wealth & Innovation, which aims to boost patient involvement, work with other aspects of NIHR infrastructure and ensure that we make NIHR funding work in our partnerships with industry for growth and wealth creation).
- The bringing together of the Themes into four 'Clusters' (Chronic Diseases; Immunity & Infection; Precision Medicine; and Technology & Big Data) to foster cross-disciplinary activities and so identify solutions to major healthcare challenges.

### 1.2 BRC3 Launch March 2017

The launch event was attended by around 100 prominent figures from the Trust, the University and partner organisations, including the newly created Oxford Health BRC. OUH was represented by the Chief Executive Dr Bruno Holthof and Medical Director Dr Tony Berendt.

As well as a presentation by Oxford BRC Director Prof Keith Channon looking back on the achievements of the previous 10 years and looking forward to the exciting possibilities of the next five, there were presentations by Theme Leaders Professors Adrian Hill (Vaccines), Andrew Carr (Musculoskeletal) and Barbara Casadei (Cardiovascular).

The video of the BRC launch can be found on the following link: [video made to mark the launch](#) on the <https://oxfordbrc.nihr.ac.uk>. The website also provides information on the Theme Leaders and co-Theme Leaders and the research priorities for <https://oxfordbrc.nihr.ac.uk/research-themes-overview>.

### 1.3 BRC Research Successes

- BRC supported research has shown that restricting the use of common antibiotics like ciprofloxacin had a more significant impact on reducing UK antibiotic-resistant *Clostridium difficile* (*C. diff*) cases than conducting 'deep cleaning' of hospitals.
- Researchers have started a new gene therapy clinical trial to treat X-linked retinitis pigmentosa, the most common cause of blindness in young people, and currently untreatable. In March, a 29-year-old British man became the first patient with the condition to undergo gene therapy in an operation at the Oxford Eye Hospital.
- Researchers in the BRC's Antimicrobial Resistance Theme, led by Prof Derrick Crook, showed for the first time that standard tuberculosis diagnostic tests can be replaced with a genetic test, applied to the TB bacteria in a patient's sputum, that takes less than 24 hours. It currently takes up to two months to get the full diagnostic information for a patient with TB.
- A study found that the SEND (System for Electronic Notification and Documentation) project, to replace bedside paper charts with tablet computers in OUH hospitals had reduced the typical time taken to input patients' vital signs by up to 30%.
- In September, the robotic retinal dissection device (R2D2) clinical trial made international headlines by becoming the first to use a robot to assist surgery inside the eye. Surgeons used the remotely controlled robot to lift a membrane 100th of a millimetre thick from the retina at

the back of the eye. In December, in another world first, the robot was used to inject a drug into the back of the eye, using local anaesthesia. The trials were led by BRC Surgical Innovation Lead, Prof Robert MacLaren.

- Oxford BRC-funded research showed that genetic differences help to explain why some babies are born bigger than others, and how these differences can influence an individual's chances of developing conditions such as type 2 diabetes or heart disease later in life.
- The unique Oxford Vascular Study (OXVASC), a BRC-funded project that studies all acute vascular events, such as strokes and heart attacks, recruited its 10,000<sup>th</sup> Oxfordshire participant. The study, begun in 2002, has provided vital data on the frequency, time-trends, causes and outcomes of heart attacks, strokes, TIAs, aneurysms and other circulatory problems. To date more than 200 scientific papers have been published, some leading to major changes in clinical practice locally, nationally and internationally.
- A ground-breaking study, supported by Oxford BRC, discovered improved methods to interpret the significance of gene mutations in patients, meaning more diagnoses could be made through genetic testing in future. Comparing genetic data from nearly 8,000 cardiomyopathy patients, the researchers aimed to reassess the role that variants in different genes play in causing the heart condition.
- Oxford researchers have found a way to help the early detection of ovarian cancer and identified an enzyme that plays a major role in making ovarian cancer spread. The team found that levels of the protein SOX2 are much higher in the fallopian tubes of people with ovarian cancer and those at high risk of developing the disease.
- A BRC-funded study confirmed that a treatment developed by Oxfordshire company Immunocore Ltd can remove HIV from its preferred hiding place in laboratory conditions, offering hope of a viable treatment. The research looked at the effectiveness of novel engineered immune-mobilising T cell receptors-based drugs ('ImmTAVs'), designed to clear HIV-infected cells from areas where they lie dormant.
- A study by The George Institute for Global Health, supported by the BRC, found that high blood pressure could increase the risk of developing vascular dementia by 62%. The study analysed the medical records of more than four million people.
- A research team led by Prof Peter Rothwell found that immediate self-treatment with aspirin when patients experience stroke-like symptoms could substantially reduce the risk of major stroke over the next few days.
- Giving daily doses of statins for a few days before and after heart surgery does not prevent heart muscle damage or the development of atrial fibrillation (AF), and can increase the risk of kidney damage, reported in a major international clinical trial led by Prof Barbara Casadei and co-funded by the Oxford BRC.

#### **1.4 ISO Accreditation**

The BRC operations team achieved a further renewal of the ISO9001 designation in March 2017, this extends until 2018 and will have an annual external audit against the standard.

#### **1.5 NIHR Oxford BRC Annual Report 2016-17**

The BRC operations team submitted its final annual report in May 2017 to the National Institute for Health Research. All 14 research Themes of the NIHR Oxford BRC have made excellent progress in addressing the aims and objectives of the BRC. There have been no changes to the strategy. The Themes have published >440 papers acknowledging the NIHR Oxford Biomedical Research Centre in peer reviewed journals during 2016-17 including papers in Nature, Nature Genetics, The Lancet, BMJ and New England Journal of Medicine

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and have attracted over £100M of external funding.

## 1.6 BRC Research Impact

The BRC team was involved in the publication of a high profile paper highlighting the impact and value of the NIHR Oxford Biomedical Research Centre:

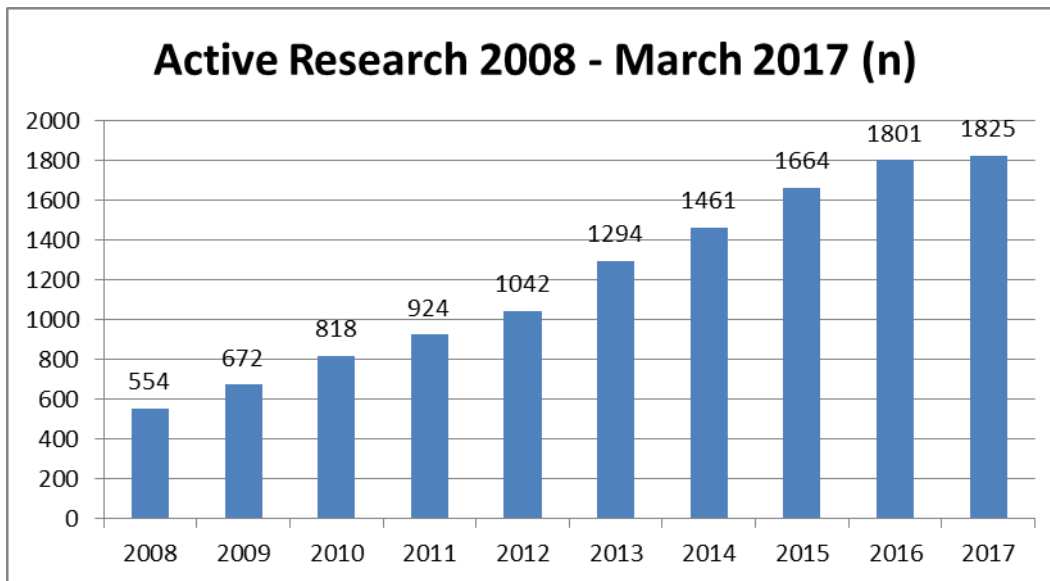
### **Does a biomedical research centre affect patient care in local hospitals?**

[Lichten CA](#)<sup>1</sup>, [Marsden G](#)<sup>2</sup>, [Pollitt A](#)<sup>3</sup>, [Kiparoglou V](#)<sup>4</sup>, [Channon KM](#)<sup>4</sup>, [Sussex J](#)<sup>5</sup>.  
[Health Res Policy Syst.](#) 2017 Jan 21;15(1):2. doi: 10.1186/s12961-016-0163-7.

2. OUH Research Activity

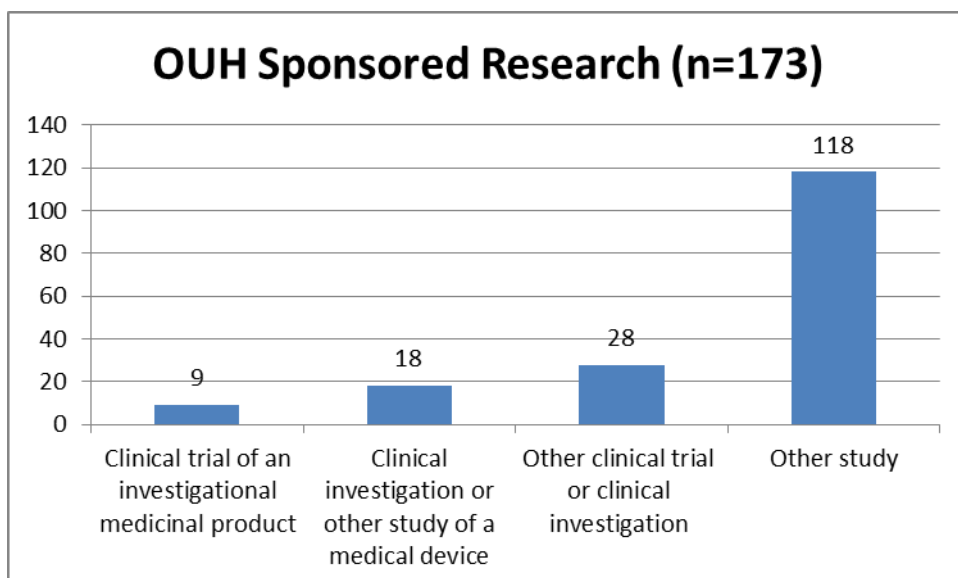
The volume of active research studies continues to increase with a tripling of research studies of all types, since 2008, such that OUH now hosts more than 1800 active research studies (see Figure 1).

Figure 1.



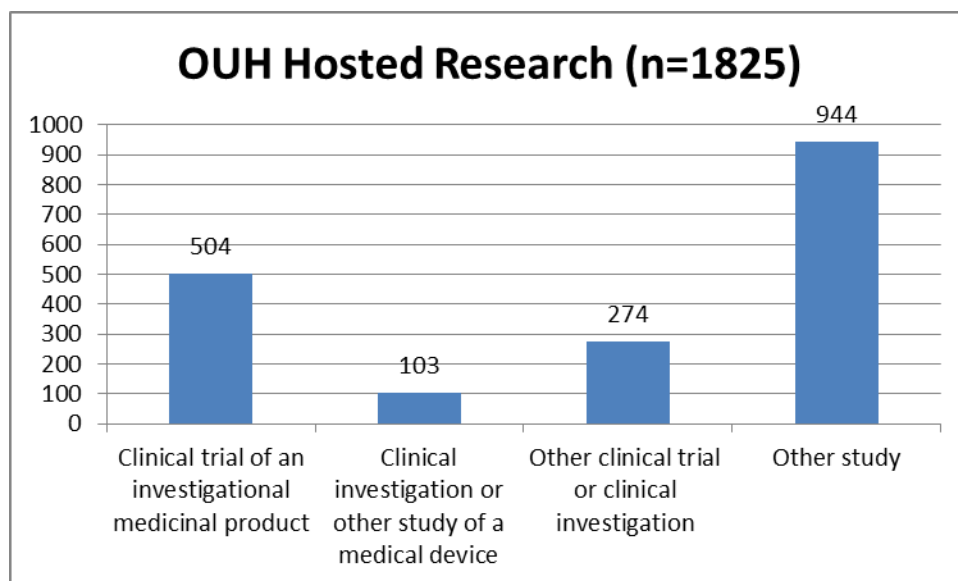
This number of studies can be analysed according to the nature of the research and whether it is **hosted** (i.e. OUH is the NHS organisation providing the clinical environment, capabilities and patient care) or **Sponsored** (i.e. OUH takes legal responsibility for the conduct of the study, as well as hosting), and whether the study is a Clinical Trial of an Investigational Medicinal Product (CTIMP), or is a non- interventional study (see Figures 2 and 3)

Figure 2.



The OUHT sponsored CTIMPs are the most resource intensive to the Governance team; with all interventional trials (sponsored and hosted) being the primary focus for reporting of OUHT performance to NIHR.

Figure 3.



The majority of OUH hosted studies are not CTIMPs, and are sponsored by organisations other than OUH (e.g. University of Oxford, commercial partners, other NHS Trusts, other universities).

### 3. Clinical Research Performance

#### 3.1 Background

The Government's Plan for Growth, published in March 2011, aimed to increase efficiency in initiation and delivery of clinical research, focusing on recruitment of the first patient to clinical trials within 70 days of receiving a valid protocol; and delivery of commercial clinical trials to time and target. It was stated that from 2013 there would be funding implications for underachieving Trusts.

The NIHR continues to place emphasis on reporting metrics for the approvals and initiation of clinical studies, which are used for monitoring the R&D performance of NHS Trusts. Attainment of key metrics is a requirement for NIHR funding, including BRCs/BRUs, and performance metrics are published for each NHS Trust receiving NIHR funding.

The Trust is also required to publish the information regarding its performance to these metrics in a readily accessible page on the website, as required by NIHR.

#### 3.2 Summary of Performance for Q4 2016/2017

##### 3.2.1 Data Completion

A full set of data was obtained and submitted within the specified timelines and published.

##### 3.2.2 70 Day Benchmark

This metric applies to all interventional trials and relates to the time taken to set up a study

and grant permission within a Trust; and, once that permission has been granted, the time by the research team to recruit the first patient (with a combined target of no more than 70 calendar days).

R&D staff work with study teams to ensure that they recruit within the required timescale prior to each NIHR submission.

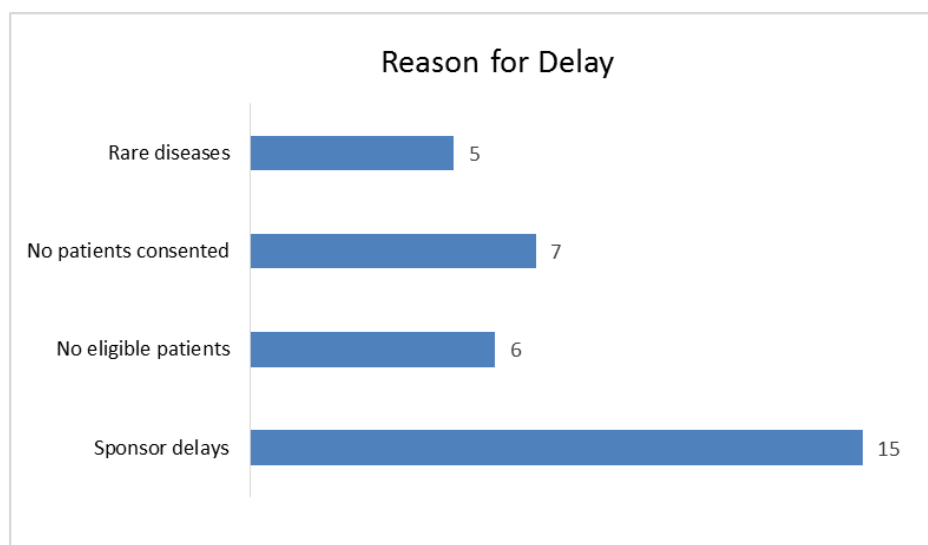
Data submitted is assessed and ‘adjusted’ according to the reasons provided for not meeting the benchmark. For example, if a trial involving rare diseases fails to recruit to the benchmark, this reason is deemed by NIHR to be acceptable and is therefore ‘adjusted’ out of the performance data. Table 1 shows this ‘adjusted’ performance.

Table 1.

	Adjusted % meeting benchmark
Q3 13/14	34.7
Q4 13/14	42.4
Q1 14/15	53.3
Q2 14/15	70.3
Q3 14/15	95.0
Q4 14/15	100
Q1 15/16	100
Q2 15/16	100
Q3 15/16	100
Q4 15/16	99
Q1 16/17	100
Q2 16/17	100
Q3 16/17	100
Q4 16/17	92.5 (change of HRA reporting)

A total of 95 studies submitted for Q4 16-17, of which 30 did not meet the 70 day benchmark target, whilst 53 met and 12 have not yet passed the 70 day target. The different reasons for not meeting the target are summarized in Figure 4.

Figure 4. Reported reason for delay for the studies not meeting benchmark





### 3.2.2. Commercial Trials Recruitment to Time and Target

This metric applies to trials with a commercial sponsor and relates to recruitment numbers within the time period specified in the agreed contract.

NIHR evaluation of this metric is limited to closed trials and so improvements in R&D processes will take time to translate to improved metric performance. It is not clear whether any penalties will be imposed, in the future, for showing little or no improvement in this metric.

Table 2.

Period	Number of reported trials	% of evaluable trials meeting recruitment target
Q3 12/13	150	46.6
Q4 12/13	157	52.3
Q1 13/14	162	50.5
Q2 13/14	191	47.4
Q3 13/14	198	46.0
Q4 13/14	181	40.5
Q1 14/15	186	49.0
Q2 14/15	176	55.0
Q3 14/15	171	57.4
Q4 14/15	204	64.7
Q1 15/16	224	58.4
Q2 15/16	226	57.9
Q3 15/16	220	61.4
		% Trials Meeting Time and Target / Total Trials
Q4 15/16	53 (change of dataset)	49.1
Q1 16/17	69	57.6
Q2 16/17	60	56.9
Q3 16/17	63	65.1
Q4 16 17	54	67.9

Accurate feasibility assessments are key to successful recruitment to time and target a review has been completed of the reasons given why studies fail to meet their recruitment criteria for the last submission Q4 16 – 17.

The reports from the NIHR analyses the “To Time and Target” Data in different ways and it is not entirely clear, at present, which calculation they are likely to focus on when assessing overall delivery of research performance.

The data for the delivery metric have been reviewed, with a view to identifying how the current rate of improvement can be increased. Around 50% of reasons for missing the target recruitment were found to be due to sponsor actions. The other 50% were due to the participant group being within a rare disease category; strict inclusion criteria; or no eligible participants giving consent. The latter reasons could be seen to indicate that researchers should be encouraged to pay further attention to their feasibility assessment, to ensure that they are not over-ambitious. JRO staff are working to address this for forthcoming trials.

#### **4. Strategies to Enhance and Accelerate Clinical Trials Performance**

The R&D Team continues to develop new strategies and processes, working with new national initiatives as they are implemented. The overall objective being to continue to maintain and improve the OUH performance in respect of the NIHR metrics for the initiation and delivery of clinical research.

The Research Portfolio Manager system, Studyline, continues to be developed and is proving to be an invaluable tool for the management of clinical research performance, by more rapidly highlighting timelines in the performance of the JRO and clinical research teams. Studyline facilitates a proactive approach to the management of data, so that outliers can be identified and addressed, within a time period that will impact upon the data submitted to NIHR.

##### **4.1 Prioritising Clinical Research Performance in the OUH Clinical Divisions**

TME receives a quarterly report of OUH Clinical research performance. The OUH Clinical Divisions are crucial to effective clinical research management, governance and performance, since the clinical activity and patient flows are embedded within Divisions, and research study PIs work as either substantive or Honorary Contract holders within the Clinical Division. Work is underway to appoint Divisional R&D Managers across OUH, who will take responsibility for coordinating the clinical research portfolio and ensuring overall satisfactory performance in feasibility, study initiation and recruitment within each Division. Embedded within, and professionally accountable to the Divisions, there will be a reporting line into the Joint Research Office. Two managers are now in post, in Surgery and Oncology and in the Clinical Support Services Divisions.

##### **4.2 Incorporation of Clinical Research Performance in Statutory & Mandatory Training, and in Consultant Appraisal**

The R&D Team provide both face-to-face and on-line training modules in Good Clinical Practice (GCP) for all clinical research PIs and for other researchers, to be undertaken in accordance with OUH policies. A video film is currently being developed to be incorporated into the OUH Induction Training for all staff. This aims to raise awareness of the importance of research in this Trust.

OUH local requirements for consultant medical appraisal have incorporated some aspects of reporting and assessing clinical research activity, for example evidence of up-to-date training in GCP. Working with the Medical Director, there is an opportunity to modify these local requirements to include more systematic and objective information on clinical research performance for all consultants who are PIs in research studies, for example by a requirement to include listings of all studies, with performance metrics, which are made available through the JRO's Research Portfolio Management system (Studyline).

The issues of both first patient recruitment and recruitment to time and target are highlighted whenever formal training is delivered to researchers. As part of their routine support role, the R&D Team also ensure that OUH PIs, research teams and clinical staff (and their managers) are reminded at every opportunity of the importance of maintaining the highest standards in these key performance metrics.

##### **4.3 The Health Research Authority Approvals Process**

The Health Research Authority (HRA) Approval Process was implemented fully in April 2016. This is the new process for research approval in the NHS in England that brings together review of governance and legislative compliance with the independent ethics review. The HRA states that "the new system simplifies the approvals process for research, making it easier for research studies to be set up." However, this does not remove the role of local R&D offices, as the HRA

requires their focus to change to ensuring that Trusts have appropriate Capacity and Capability to undertake each project as it is submitted.

HRA approval represented a significant change to research governance nationally, and has already had a dramatic effect on the business of the Joint Research Office (JRO), both for the University and Trust. Initial difficulties with implementation have been allayed through good communications with representatives of HRA.

In order to support the HRA, managers in the JRO take every opportunity to be involved in consultations and updates on the process at a national level: Oxford is represented in groups such as the NIHR Research Champions; the Research & Development Forum Strategic Group; The HRA Sponsor Reference Group; HRA Amendment Working Group and the HRA model Non- Commercial Agreement (mNCA) redraft group.

The level of governance review within the JRO is being tailored to the level of maturity of the HRA processes. It is intended that this will reduce over time, to a point where there will be a light-touch review of the protocol and participant information sheets, ensuring that the regulatory responsibilities of the Trust, as a host organisation are fulfilled in the case of Clinical Trials of Investigational Medicinal Products (CTIMP).

The Trust will continue to provide a letter to the Principal Investigator (PI), to authorise the conduct of the research within the Trust; the use of Trust resources; their responsibility for the care of the participants taking part in that research study; and detailing their targets and timelines for the delivery of that research. This complements the NHS Permission provided by the HRA and the agreement between the Trust and the Sponsor.

## 5. Research Management and Governance

### 5.1 Background – NHS Research Governance

Research governance refers to the framework in OUH to manage the research process from end to end, to ensure that research is undertaken in a safe, appropriate and ethical manner, in accordance with national guidance and applicable laws to ensure that maximum benefit is derived from research of public and patients. These include:

- **The Health Research Authority (HRA)** that has responsibility for both the HRA Approval Process in England and the National Research Ethics Service (NRES), which is responsible for all Research Ethics Committees (RECs).
- **The NHS Research Governance Framework (RGF)** that sets out a framework for the governance of research in health and social care. This includes clinical and non-clinical research; research undertaken by NHS or social care staff using the resources of health and social care organisations; and any research undertaken by industry, charities, research councils and universities within the health and social care systems that might have an impact on the quality of those services. The HRA intends to replace the RGF with a new simplified framework, the timelines for this are not clear.
- **EU Clinical Trials Directive (2001/20/EC)** provides a framework which sets out how clinical trials investigating the safety or efficacy of a medicinal product in humans must be conducted. The EU Clinical Trials Directive was transposed into UK Law as the Medicines for Human Use (Clinical Trials) Regulations 2004 and came into force on 1st May 2004, forming the basis for the UK Clinical Trials Regulations 2004.

### 5.2 Local Frameworks for R&D Governance, Training and Monitoring

Locally, clinical research is governed by a number of OUH Trust policies:

- Safety Reporting in Clinical Research
- Sponsorship of Clinical Research Studies
- Trust Management Approval for Clinical Research
- Research Protocol Amendments
- Monitoring and Audit of Research Studies
- Research Grants Policy and Procedures
- Management of Intellectual Property
- Integrity in Research
- Receipt, Storage and Handling of Investigational Medicinal Products

These policies are underpinned by a suite of Standard Operating Procedures (SOP) within R&D. Policies and SOPs are updated in response to national and local developments.

The policies are all available on the OUH website and specific attention is drawn to them during Good Clinical Practice (GCP) training. The content and requirements of the policies are also covered within this training. Through collaboration with the University of Oxford Clinical Trials and Research Governance team (CTRG), GCP training is provided to cover all research-related legislation and GCP; courses being designed for both staff new to trials and an update for experienced researchers. GCP training is a legal requirement of the Regulations and the Research Governance Framework. All researchers, in the Trust and the University, are required to have undertaken this training every three years as a minimum.

A training course is provided for clinical researchers, specifically designed for those not engaged in the conduct of a CTIMP. Informal training is provided in the form of advice and support to researchers and their teams.

### **5.3 Strengthening Research Governance in OUH**

OUHT has a very large research portfolio and has established a robust approach to governance in accordance with national standards.

The R&D Governance team ensure that all Clinical Trials of Investigational Medicinal Products (CTIMP) and device trials, for which the Trust has taken on the role of Sponsor, are monitored, to assure the Trust of compliance with the relevant regulations. In addition, a number of hosted CTIMPs are selected for audit, either where concerns have been raised, or according to a risk assessment. For a selection of research studies, compliance checks are undertaken periodically. Such checks involve assessing levels of compliance in specific areas of research conduct, e.g. informed consent procedures and safety reporting requirements.

To maintain the highest standards, all members of staff in research must be aware of the need to comply with the policies and procedures for research governance in the Trust. This is most easily achieved by ensuring that R&D activities are fully integrated, reported and monitored in the Clinical Divisions. Divisional R&D Managers have been appointed with a mandate to promote research, oversee performance and ensure that research active staff have adequate training to undertake trials and studies in a safe manner. This effective local/divisional implementation and monitoring of governance policies will promote patient safety in OUHT.

Greater awareness of R&D governance, for training in GCP and the requirements of R&D SOPs and policies could be achieved through Statutory and Mandatory Training, through Appraisal and through Divisional audit and training activities, the goal being to ensure that the vast majority of clinicians are able to support well governed research by understanding the processes that should be demonstrable by investigators in the clinical environment.

## 6. R &amp; D Finance

## 6.1 Year End Financial Position

For the financial year 2016-17, the OUHFT reported a breakeven financial position for Research and Development. The budget includes income and spend for major OUH-OU NIHR infrastructure programmes (BRC, BRU, LCRN etc).

As detailed in the table below, in total for Research and Development for the Trust, actual income of £55.3m was recovered and expenditure of an equal amount was committed (£55.3m).

OUHFT R&D only	Outturn 2016-17		
	Plan £m	Actual £m	Variance £m
<b>Income</b>			
Other Income	52.6	55.3	2.7
<b>Total Income</b>	<b>52.6</b>	<b>55.3</b>	<b>2.7</b>
<b>Expenditure</b>			
Pay	-40.1	-38.6	1.5
Non-Pay	-12.5	-16.7	-4.2
<b>Total Expenditure</b>	<b>-52.6</b>	<b>-55.3</b>	<b>-2.7</b>
<b>EBITDA</b>	<b>0</b>	<b>0</b>	<b>0</b>

## 6.2 Financial Planning for 2017-18

For the financial year, the Trust has set an annual income and expenditure plan of £52.3m for Research and Development. The plan represents:

- NIHR funded schemes of £41.7m (80% of total budget)
- £10.6m for balances generated from R&D activities and infrastructure costs

The overall plan for 2017-18 reflects a reduction to NIHR funding levels of circa £1.9m from 2016-17. This is due in part to:

- a) Reduction in BRC funding of £1.3m to reflect the phasing of the new 5 year award and the 50% cap on funding for new research Themes in year 1 only.
- b) Reduction of Trust Research Capability Funding (RCF) of £1.5m (see below).
- c) Additional Local Clinical Research Network funding of £1m.
- d) Reduction of £0.1m for the new 5 year Clinical Research Facility award.

## 6.3 Research Capability Funding

Research Capability Funding (RCF) is allocated to research active NHS organisations who are in receipt of major NIHR programme awards and have NIHR Senior Investigators associated with them. The Trust has received an annual allocation of £4m for the financial year 2017-18. This funding has been reduced by 27% compared to the funding received in 2016-17 (from £5.5m). The reduction was not, in any part due to any performance metric or benchmark issues, but reflects the pressure on NIHR budgets overall and their decision to set a “cap” of £4m funding allocated against the largest research active Trusts.

RCF will be used across the OUH-UoO partnership in line with NIHR policy and guidelines.

## 7. Joint Research Office

### 7.1 Accommodation

The JRO teams need to vacate their offices at Block 60 at the Churchill Hospital, which are in a poor state of repair and are due to be demolished as part of a major redevelopment by the Trust. Unfortunately it has not been possible to identify suitable alternative premises to accommodate all the JRO teams together in one place, so the Trust teams will be moving to Unipart House, Cowley and the UoO teams to Boundary Brook House in Headington. The timelines for both moves are currently under discussion. The teams’ requirements will include reciprocal arrangements for accessing facilities such as hot-desks, meeting rooms and videoconferencing facilities. These will be essential to support the new working practices that will be necessary to maintain the existing effective and important relationships between the JRO’s OUH and UoO staff, as well as OUH staff and researchers on the clinical campuses.

The move to new accommodation presents opportunities for the future development of the JRO and its relationship with other related groups in Oxford. In particular, the Thames Valley and South Midlands LCRN (which is hosted by OUH), as well as R&D staff from Oxford Health NHS FT, many of whose staff will be based alongside the OUH JRO teams at Unipart House. Facilities at Unipart House will also be made available for regular use by the UoO JRO teams, as well as visiting colleagues from the AHSC and Oxford Brookes University. With careful management by the JRO Heads of Teams, these new arrangements should facilitate more effective working relationships and better sharing of expertise, leading to improvements in understanding and cooperation with our local partner organisations, to the benefit of the clinical research community in Oxford.

## 7.2 JRO workshop

The JRO Heads of Teams organised and hosted an away day workshop at the Blavatnik School of Government in March 2017, on the theme 'Enhancing interconnectivity across the Oxford clinical research landscape'. This was attended by more than 90 people, including staff from Oxford University Innovation and the University's Intellectual Property Rights Team as well as around 20 from the other AHSC partners (Oxford Health NHS FT and Oxford Brookes University) and the LCRN.

The workshop included several networking opportunities as well as exercises in which small teams of staff drawn from the different organisations were required to work closely together. There was also a panel discussion featuring senior executives from the Trust and UoO, which was very well received. Feedback from participants was very positive, with many highlighting how much they had enjoyed getting to know more about the other organisations and their staff – often being able to put a face to a name for the first time. The JRO Heads of Teams, as well as the leaders of the other organisations involved, were pleased with both the tone and the substance of the workshop, which will help set the scene for greater cooperation in the near future.

## 7.3 Studyline project and portfolio management system

The Oxford Joint Research Office has developed the Studyline project and portfolio management system to help the Trust and University of Oxford manage their large portfolios of clinical research.

Formerly known as RPM (Research Portfolio Manager), the system helps the JRO undertake its clinical research management and oversight activities, e.g. sponsorship review, funding approval, ethical opinion, site feasibility, capacity and capability, participant recruitment and monitoring. As well as providing good governance, Studyline helps the Trust to ensure meets its national performance metrics set by the NIHR, e.g. 70 day benchmark for recruiting first participant and ongoing participant recruitment to time and target.

This year the system has been extended to support other trusts in the NIHR Thames Valley and South Midlands CRN. Having been selected as the CRN's Local Portfolio Management System (LPMS), Studyline is now being rolled out to our partner organisations. The system is now live in Oxford Health and Milton Keynes University Hospital and will be rolled out to Buckinghamshire Healthcare NHS Trust, Royal Berkshire and Berkshire Healthcare NHS Foundation Trusts in the coming months. We are developing an interface with the NIHR's Central Portfolio Management System (CPMS) so that performance data from each Trust can be readily reported to the NIHR.

The JRO will continue to develop the Studyline system to add new functionality and extend its reach to important research stakeholders such as Trust service departments and Investigators. We also have plans to add a separate recruitment module to help research teams proactively manage their participant recruitment.

## 8. Recommendation

The Trust Board is asked to note this report.

**Dr Tony Berendt**  
**Medical Director**

Report prepared by:  
Professor Keith Channon  
OUH Director of R&D